

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

Civil Action: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL ACTIONS

**REPLY MEMORANDUM IN SUPPORT OF
AMGEN INC.'S MOTION TO DISMISS**

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Defendant, Amgen Inc. ("Amgen") submits this memorandum in reply to Plaintiffs' opposition to Amgen's Motion to Dismiss the Master Consolidated Class Action Complaint (the "Complaint") filed in this matter.

I. Plaintiffs' Opposition Fails Even to Address Amgen's Motion to Dismiss Under Rule 9(b).

In their one paragraph opposition to Amgen's motion, Plaintiffs fail even to respond to, let alone satisfactorily address, what is obvious on the face of the Complaint: that, as to Amgen, the Complaint absolutely fails to comply with Rule 9(b)'s pleading requirements. Instead, Plaintiffs are content to smear Amgen by relying on the single allegation that the company "engaged in an ongoing deliberate scheme to inflate AWP's." Complaint ¶ 192. Such wholly conclusory allegations are insufficient under Rule 9(b), and Plaintiffs' silence in response to Amgen's motion is telling.

As to Amgen, Plaintiffs' lack of compliance with Rule 9(b) is not even a close call. Unlike their broader opposition to other defendants' motions, ^{1/} Plaintiffs cannot even point to allegations, for example:

- that Amgen has been involved in, targeted by, or even questioned by the government regarding its calculation of AWP (*compare* Plaintiffs' Consolidated Opposition at 5, 11);
- that Congress has identified any concerns regarding the pricing or marketing of any Amgen product (*compare id.* at 5);

^{1/} Amgen does not mean to suggest that the allegations as to any other defendant comply with Rule 9(b). Indeed, Amgen has joined in the consolidated motion filed by defendants, in which defendants have challenged aspects of the Complaint, including Plaintiffs' RICO allegations and allegations relating to PBMs, as inadequate under the rule.

- a single example of how Amgen might have falsely inflated AWP (*compare id.* at 6-7, 32); or
- any examples of any other improper conduct by Amgen in the marketing of its products (*compare id.* at 32).

Plaintiffs do not make any such allegations as to Amgen even after having had ample opportunity to investigate. Instead, Plaintiffs are seemingly content to rely on examples of alleged misconduct provided “at the end of almost every Defendant-specific section.” *Id.* at 32 (emphasis added). In the context of Rule 9(b), and as to Amgen, “almost” is not good enough.

Nor can Plaintiffs find safe harbor in the broad allegations of misconduct by “defendants” generally, as they have sought to do in response to other defendants’ motions. *See* Plaintiffs’ Consolidated Memorandum at 58. Rule 9(b) requires minimally sufficient factual allegations as to each defendant. *See, e.g., Goebel v. Schmid Bros.*, 871 F.Supp. 68, 73 (D. Mass. 1994) (citing *Fleet Credit Corp. v. Sion*, 893 F.2d 441, 444-445 (1st Cir. 1990)). *See generally* Memorandum in Support of Defendant Amgen Inc.’s Motion to Dismiss at 4-5 and n.5. Rather than address these authorities, Plaintiffs choose simply to ignore them.

As this Court has recognized, Rule 9(b) serves two important purposes. First, it is intended to “enabl[e] defendants to prepare meaningful defenses to charges of fraud.” *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 46 (D. Mass. 2001). Second, and as importantly, it serves a gatekeeping function, to “prevent[] conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and [to] protect[] defendants from groundless charges that may damage their reputations.” *Id.* (citing *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 292 (1st Cir. 1987)). The Complaint, as to Amgen, serves neither objective.

II. Plaintiffs’ Allegations Relating to EPOGEN® Must be Dismissed.

Plaintiffs’ claims must also be dismissed to the extent that they seek recovery based upon Medicare reimbursements and co-payments for EPOGEN® that are not even based

on AWP. The Medicare reimbursement rate for EPOGEN® administered by dialysis centers – virtually all of Amgen’s sales – is prescribed by Congress at a flat \$10 per 1,000 units. ^{2/} That rate, which has remained unchanged for nearly a decade, is not based on AWP, and thus cannot conceivably be manipulated or inflated. *See* 42 U.S.C. § 1395rr(b)(11)(B). Indeed, Plaintiffs do not contend otherwise. *See* Plaintiffs’ Consolidated Memorandum at 56.

Even to the limited extent that Plaintiffs claim that reimbursement for EPOGEN® might be AWP-based (where, for example, it is administered by a physician), Plaintiffs cannot conceivably contend that they have been misled. Unlike any other product identified in the Complaint, the reimbursement rate set by Congress and CMS for EPOGEN® is both publicly available and widely known. To the extent that Amgen’s reported price for purposes of calculating AWP differed from that rate, Plaintiffs simply cannot plausibly claim that they were deceived into paying falsely inflated co-payments for EPOGEN®. ^{3/}

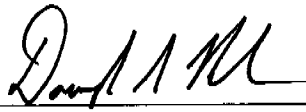
CONCLUSION

For the foregoing reasons, and for the reasons set forth in Amgen’s initial motion and memorandum, Amgen requests that the Complaint against it be dismissed with prejudice.

^{2/} Physician office use of EPOGEN® in treatment of dialysis patients is extremely rare, if it exists at all, because EPOGEN® is administered during dialysis at dialysis facilities. Patients who are capable of self-administering dialysis can also self-administer EPOGEN®, in which the statutory rate is paid.

^{3/} Amgen notes, in this regard, that plaintiffs do not even allege that any plaintiff actually purchased either of Amgen’s named products, EPOGEN® or Neupogen®, and in this regard relies upon and adopts the arguments set out in Bayer Corporation’s reply to Plaintiffs’ opposition.

Respectfully submitted,



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